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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,887	11/13/2003	Jacqueline E. Heard	MBI-0058CIP	5720
47550 7590 05/26/2010 MENDEL BIOTECHNOLOGY C/O MOFO SF 425 MARKET STREET SAN FRANCISCO, CA 94105				
EXAMINER KRUSE, DAVID H				
ART UNIT 1638		PAPER NUMBER		
MAIL DATE 05/26/2010		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/714,887

**Applicant(s)**

HEARD ET AL.

**Examiner**

David H. Kruse

**Art Unit**

1638

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 71-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 1/27/2010

**STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Arguments filed on 5 February 2010.
2. The IDS's filed on 27 January 2010 have been considered, signed copies are attached hereto.
3. The Declaration under 37 CFR 1.132 of T. Lynne Reuber has been fully considered and is addressed below.
4. The rejection under 35 U.S.C. 112, first paragraph, for New Matter in claim 71 (specifically) is withdrawn in view of Applicants' amendments, and showing of support in the Remarks, pages 5-6.
5. The rejection under 35 U.S.C. 112, first paragraph, for Scope of Enablement is withdrawn in view of Applicants' arguments.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 71-73 and 75-79 remain rejected and claims 80 and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last

Office action mailed 9 November 2009. Applicant's arguments filed 5 February 2010 have been fully considered but they are not persuasive.

Applicants' claim a transgenic plant with greater tolerance to osmotic stress, salt and/or water deprivation comprising a recombinant polynucleotide encoding a polypeptide that is at least 60% identical to SEQ ID NO: 4.

Applicants describe a transgenic plant with greater tolerance to osmotic stress, salt and/or water deprivation comprising a recombinant polynucleotide encoding a polypeptide comprising SEQ ID NO: 4.

Applicants do not describe the genus of claimed transgenic plants with greater tolerance to osmotic stress, salt and/or water deprivation comprising a recombinant polynucleotide encoding a polypeptide that is at least 60% identical to SEQ ID NO: 4. In fact, Applicants describe only one other species of polypeptide that is at least 60% identical to SEQ ID NO: 4, that being SEQ ID NO: 212 (G3810) at 62.7% identical. Applicants' second species falls at the far extreme of the claimed genus and does not describe the variation within the claimed genus.

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed.

Applicants argue that they have provided an alignment (with SEQ ID NO: 4) and G3811 (SEQ ID NO: 214) that shows that G3811 and G922 share 61% sequence identity in the response filed 24 August 2009 (page 6 of the Arguments). In addition, the instant response provides additional alignments with G3824, G3813, G3814 and G3827. Applicants' evidence fails to support their argument of adequate written description

because the alignments provided are directed to partial amino acid sequences and not full length alignments. The G3811 alignment is only from amino acids 37-482 of instant SEQ ID NO: 4. The alignment with G3824 in the instant response is only from amino acids 91-482 of instant SEQ ID NO: 4. Hence, the evidence does not support Applicants' assertion that they had described an adequate number of species that would represent the variation within the claimed genus.

Applicants argue that it was well known in the art that protein functions can be classified using phylogenetic analysis (page 7, 3rd paragraph) and that the claimed genus belongs to the SCR gene family, which is part of GRAS gene family of transcription factors where the conserved domains are art-recognized as important for the activity of this family of transcription factors and that proteins in the GRAS family are transcription factors that seem to be involved in development and other processes (paragraph spanning pages 7-8 of the Arguments). These arguments are not found to be persuasive because with transcription factors, phylogenetic relationships are not adequate to describe any specific function to the transcription factor. "Development and other processes" are not specific functions.

Applicants argue that they believe that in view of the significant structure/function relationships disclosed in the cited references and conserved domain disclosed in the specification in combination with the disclosed working examples, one of ordinary skill in the art would recognize that the three conserved domains with high homology and the overall homology to SEQ ID NO: 4 are correlated with the function of conferring greater tolerance to water deprivation (page 9, 1<sup>st</sup> paragraph of the Remark). These arguments

are not found to be persuasive because the structure/function correlation is not persuasive for the reasons given above.

Applicants' arguments concerning Example 11B of the 2008 Written Description Training Materials are not found to be persuasive (page 10, 2<sup>nd</sup> paragraph of the Arguments). Applicants have not show a correlation between the SCR domains and greater tolerance to water deprivation in a transgenic plant within the breadth of the claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 71-79 remain rejected and claims 80-82 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Benfey *et al* (WO 97/41152) in further view of Benfey *et al* (U.S. Patent 6,411,270, filed 24 April 1997) and Pysh *et al* (1999, The Plant Journal 18(1): 111-119). This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 May 2009. Applicant's arguments filed 24 August 2009 have been fully considered but they are not persuasive.

Benfey *et al* teach a recombinant polynucleotide encoding amino acids 158-482 of instant SEQ ID NO: 4, in SCARECROW-LIKE 3 (*SRPa1* gene, Figure 9A and SEQ ID NO: 21). Benfey *et al* teach a plant transformed with said recombinant polynucleotide at claim 20. Benfey *et al* teach said transformed plant wherein the recombinant

polynucleotide is expressed in roots at claim 23. While Benfey *et al* do not specifically teach overexpression of said polynucleotide confers to the transgenic plant greater tolerance to osmotic stress, salt and/or water deprivation, Benfey *et al* do teach that overexpression of said polynucleotide would result in modified root development (claim 18).

Benfey *et al* do not teach a polynucleotide or plant transformed therewith encoding instant SEQ ID NO: 4.

Pysh *et al* teach a recombinant polynucleotide encoding amino acids 158-482 of instant SEQ ID NO: 4, in *SCARECROW-LIKE 3* (Table 1 on page 113 and Figure 1 on page 114). Pysh *et al* teach that *SCL3* is expressed in roots (Figure 3 on page 116). Provisional application 60/125,814 to which the instant Application claims benefit of only discloses a partial polypeptide sequence, which in fact is shorter than that taught by Pysh.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Benfey *et al* to isolate the complete *SCARECROW-LIKE 3* transcription factor encoding polynucleotide and transform a plant therewith, particularly with a constitutive or a tissue specific promoter. Pysh *et al* had taught where the *SCARECROW-LIKE 3* transcription factor is naturally expressed. The use of a *SCL3* transgene to modify root architecture in a transgenic plant would have been obvious to one of ordinary skill in the instant art. At the time of Applicants' invention, one of ordinary skill in the art would have had a reasonable

expectation of success in isolating the complete *SCL3* transgene and produce a transgenic plant therewith.

Applicants argue that the present claim is limited to sequences that have a first conserved domain that is at least 68% of amino acids 134-199, therefore, the Benfey sequence falls out of the claimed scope (page 15 of the Arguments). While this is a matter of fact, the instant rejection is not under 35 U.S.C. 102. The Examiner maintains it would have been obvious in view of the teachings of Benfey to isolate a polynucleotide encoding the entire *SCL3* gene.

Applicants argue that although Pysh did show that *SCL3* was expressed in root by RNA blot analysis and estimated the band in the blot as 1.8 Kb, Pysh did not disclose the complete sequence of *SCL3* (syn. *SRPa3*). Applicants argue that a band in a DNA gel can hardly be regarded as representing any specific structure of a full length DNA molecule. Applicants argue that Pysh did not teach the presently claimed sequences. Applicants argue that the only related sequence in Pysh's disclosure lacks the 157 amino acids of the instant SEQ ID NO: 4, the missing part includes the 24 amino acids that make up the first conserved SCR domain (please see the previous response regarding the partial sequence). Applicants argue that combining Pysh and Benfey would not cure the deficiency of lacking the structure of the full length sequence (paragraph spanning pages 15-16 of the Arguments). These arguments are not found to be persuasive because Benfey had acknowledged that the *SRPa3* gene was partially sequenced (page 12, lines 23-25), but it would have been obvious and within the means of one of ordinary skill in the art at the time of Applicants' invention to isolate the



complete coding sequence and transform a plant therewith. Benfey teaches transforming a plant with an isolated nucleic acid encoding the SRPa3 at claims 1, 2, 20 and 23 (SEQ ID NOs: 20 and 21).

Applicants argue that transgenic plants claimed in the instant application not only comprise sequences with the predictable structural elements in terms of the conserved domains and overall protein structure by percent identity through BLAST, but also have greater tolerance to water deprivation compared to control plants. Applicants argue that The Office action did not take into account the functional limitation that is crucial for identifying the claimed genus. Applicants argue that Benfey's prediction that SCR proteins have the abilities to confer thicker root does not render plants that over-express SCR proteins and have greater tolerance to water deficit obvious. 35 U.S.C. 103(a) demands consideration of "the subject matter sought to be patented...as a whole" (MPEP 2141). Applicants argue that The Office action failed to reason why water deprivation tolerance is obvious in view of the plants transformed with the partial sequence or the full length counterpart and having thicker root development. (paragraph spanning pages 16-17 of the Arguments). Applicants' arguments are not found to be fully persuasive. First the claims are not limited to overexpression. Root development was well known in the plant arts as being critical to water deprivation tolerance. In addition, the Examiner has considered the subject matter sought to be patented as a whole. One of ordinary skill in the instant art would through the natural course of experimentation transform a plant with a transcription factor encoding polynucleotide and test the plant for modified morphology and physiology. One of ordinary skill in the

instant art would have made a large number of transgenic plants realizing that not all transformants will functionally express a transgene.

Applicants argue that it is not the transgenic plants transformed with the full length sequence of G922 that were claimed by the instant application, but rather a specific subset of those that have water deficit tolerance. Applicants argue that even if the complete sequence of G922 were obtainable before Applicants' disclosure, no trait of water deficit tolerance has ever been suggested for transgenic plants transformed with G922 polynucleotide by Benfey or Pysh. Applicants argue that as we have seen with the evidence presented in Dr. Reuber's declaration submitted previously to the Office, the instantly claimed genus, i.e., plants overexpressing G922 (SEQ ID NO: 4) and having greater water deficit tolerance, do not have thicker root development; quite on the contrary, a lot of the overexpressors had less root development than control plants (page 17, 2<sup>nd</sup> paragraph of the Arguments). Applicants' arguments are not found to be persuasive because it is the G922 transgene species that the Examiner asserts would have been obvious at the time of Applicants' invention, hence the genus would have been obvious. In addition, the Reuber Declaration teaches that 25% of the overexpressing transgenic plant demonstrated the claimed trait and the other 75% "showed no discernible difference compared to control plants" (item 5 in The Declaration). As stated above, the instant claims are not limited to overexpression. In addition, one of ordinary skill in the instant art would have made a large number of transgenic plants and hence would have made the claimed transgenic plant.

Applicants argue that the Federal Circuit has ruled that inherency cannot be "established by probabilities or possibilities" and that, the mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999). Applicants argue that the court stated that the burden falls on the examiner to "provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Applicants argue that The Office action has not provided a factual basis or technical reasoning to support a finding of inherency based on Benfey or Pysh. Applicants argue that Applicants' own experimental evidence demonstrated that greater tolerance to water deficit does not necessarily flow from overexpression of the claimed sequences (paragraph spanning pages 17-18 of the Arguments). Applicants' arguments are not fully persuasive. In *In re Robertson*, the court states that "In reversing the Board, this court relies solely on the purported failure of Wilson to teach the third fastening means.", while in the instant case Benfey had provided sufficient guidance to make the claimed invention and had provided sufficient motivation to one of ordinary skill in the art to do so. In *Ex parte Levy* the secondary reference Wyeth had taught away from the combination in a declaration, in contrast to *Ex parte Levy*, Benfey teaches using the SCL3 transcription factor to produce transgenic plants.

Applicants argue that water deficit tolerance is not necessarily present, and thus not an inherent trait or function of transgenic plants expressing SRPa3. Applicants

argue that having greater tolerance to water deficit tolerance is not predicable in plants transformed with G922 (SEQ ID NO: 3) (paragraph spanning pages 18-19 of the Arguments). Applicants argue that it is not obvious to try to make G922 transformants and test for water deprivation in view of Benfey even if the techniques and tools are available. Applicants argue in view of Benfey even if the techniques and tools are available. Applicants argue water deprivation tolerance is only one of the very large number of possible phenotypes that a plant could have and that were not suggested or tested by Benfey. Applicants argue even the combination of Benfey and Pysh fails to cure the deficiency of lacking the functional limitation of conferring greater tolerance to water deprivation. Applicants argue Benfey prophetically disclosed that SRPa3-overexpressing plants have thicker roots. Applicants argue in view of Benfey's and Pysh's disclosure, if one of ordinary skill had introduced Benfey sequences into plants and tested for thicker roots, and if he, like Applicants, observed that none of the plants had thicker root and some of them had even less root development, he would have doubts on the accuracy of the Benfey disclosure, and he would not likely pursue any further use of these transgenic plants, including testing these plants for greater tolerance to water deficit (page 19, 3<sup>rd</sup> paragraph of the Arguments). Applicants' arguments are not found to be fully persuasive. As previously stated, the instant claims are not limited to overexpression. In view of the teachings of Benfey and Pysh, one of ordinary skill in the art would have looked to changes in the morphology and function of the roots of a transformed plant thus would have looked for a limited number of phenotypes in the transgenic plants.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/  
Primary Examiner, Art Unit 1638  
24 May 2010